UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VICKIE QUAID,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
JOHNSON & JOHNSON, ORTHO-McNEIL PHARMACEUTICAL, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.'S and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	)	
Defendants.	)	

COMPLAINT AND
DEMAND FOR JURY TRIAL

Plaintiff VICKIE QUAID, by and through her attorneys of record, hereby files this Complaint and Demand for Jury Trial against Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), and Johnson & Johnson Pharmaceutical Research & Development, LLC ("Johnson & Johnson Pharmaceutical" or "Johnson & Johnson PRD") (collectively "Defendants"), and states of information and belief as follows:

INTRODUCTION

1. This case involves the fluoroquinolone antibiotic, levofloxacin.

2. Levofloxacin was designed, formulated, promoted, sold and distributed by Defendants in the United States as Levaquin from 1997 through the present.

3. Levaquin was approved by the FDA for treatment of a variety of serious infections. However, Defendants market Levaquin as a first line therapy for common bronchitis and sinusitis infections, and for which many other, safer, antibiotics are available.

4. As compared to other fluoroquinolone antibiotic drugs, Levaquin causes a higher incidence of tendon injuries, including tendon rupture, especially in persons over 60 years of age

and/or who are on corticosteroid therapy, none of which was adequately disclosed to Plaintiff and her physicians.

5. Levaquin-induced tendon injury involves the degradation of the tendon tissue, leading to severe and permanent injuries.

6. Plaintiff VICKIE QUAID suffered a severe and debilitating tendon injury after her use of the drug Levaquin.

7. This lawsuit asserts claims against Defendants for strict product liability for manufacturing and/or design defect; strict product liability for failure to warn; negligence; breach of implied and express warranties for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion, and distribution of Levaquin; fraud; violation of consumer protection and unfair trade practice laws; and unjust enrichment.

JURISDICTION

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the prescription drug Levaquin within this judicial district and because Defendants are subject to personal jurisdiction within the State of Minnesota.

PARTIES

10. Plaintiff VICKIE QUAID is a citizen and resident of Grand Saline, TX.

11. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

12. Defendant Ortho-McNeil is a Delaware corporation with its principal place of business in Raritan, New Jersey. Defendant Ortho-McNeil is a wholly owned subsidiary of Johnson & Johnson.

13. Defendant Johnson & Johnson Pharmaceutical Research & Development is a New Jersey corporation with its principal place of business in Raritan, New Jersey. Defendant Johnson & Johnson Pharmaceutical Research & Development is a wholly owned subsidiary of Johnson & Johnson and was formerly known as R.W. Johnson Pharmaceutical Research Institute.

14. Defendant Ortho-McNeil-Janssen Pharmaceuticals is a Pennsylvania Corporation, with its principal place of Business in New Jersey.

15. At all times relevant herein, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold the prescription drug Levaquin in interstate commerce and throughout the State of Minnesota. At all times relevant herein, Defendants were registered to do business in the State of Minnesota.

GENERAL FACTUAL ALLEGATIONS

16. Levaquin, Defendants' brand name for the antibiotic levofloxacin, is a broad spectrum synthetic antibacterial agent approved for use in the treatment of a variety of upper respiratory infections, urinary tract infections, prostatitis, and other bacterial infections. It was first introduced into the U.S. market in 1997.

17. Levaquin is in a class of antibiotics known as fluoroquinolones. The original quinolone antibiotics were developed in the early 1960s and soon revealed themselves as highly effective against common gram-negative bacteria, but resistance developed rapidly. Twenty

years later, in the early 1980s, fluorinated derivates of the quinolones emerged, revealing a broader, more potent antibiotic, effective against many different types of infections. These so-called second generation fluoroquinolones included norfloxacin (Noroxin), ciprofloxacin (Cipro), ofloxacin (Floxin), and pefloxacin (which was never marketed in the U.S.).

18. Although considered highly effective at killing certain bacteria, fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the market due to intolerable adverse events. For example, Omniflox (temafloxacin) was removed from the market in 1992 because of association with low blood sugar, kidney failure, and a certain rare form of anemia; Raxar and Zagam were removed because of association with QT-interval prolongation among other things; Trovan was removed from the market due to association with severe liver toxicity; and most recently, Tequin was removed from the market in 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

19. In sum, though fluoroquinolones may share certain pharmacological properties, their safety profiles can differ immensely.

A. OFLOXACIN – THE FIRST GENERATION OF LEVAQUIN

20. To understand the pharmacological properties of Levaquin, one need look no further than to Levaquin's older brother, ofloxacin (Floxin), also manufactured and distributed by Defendants.

21. Both Floxin and Levaquin were created and developed by Daiichi, a Japanese Company who holds the patent on both drugs. Daiichi assigned the patents to Defendants and gave Defendants an exclusive license to manufacture and market both of these fluoroquinolone compounds in the United States in return for royalty fees. Daiichi licenses levofloxacin to

Aventis for manufacture and market in European counties. To date, Levaquin remains one of Daiichi's best selling pharmaceuticals.

22. Daiichi ensured that the post market surveillance of levofloxacin would be tracked world-wide by creating an international database to keep track of adverse events. This database ensured that Defendants could not ignore the post market experience of levofloxacin in other countries.

23. Ofloxacin was first introduced into the Japanese market in September 1985. Defendants introduced ofloxacin, under the brand name Floxin, in the United States six years later, in 1991.

24. Even before ofloxacin was marketed in Japan, Daiichi began researching products that could be the successor of ofloxacin. Daiichi wanted to develop a newer fluoroquinolone in order to be more competitive with Cipro and the other fluoroquinolones by developing a drug with the same or better characteristics of ofloxacin that could be used both orally and by injection.

25. After many derivatives of ofloxacin were explored and synthesized, Daiichi isolated what is now known as levofloxacin. Levofloxacin is a purified version of one optically active form of ofloxacin, more specifically the L-isomer.

26. Accordingly, ofloxacin and Levaquin are pharmacologically very similar -- in fact, so similar that Defendants alleged in their New Drug Application for Levaquin that the safety profile of Levaquin would be expected to mirror that of ofloxacin.

27. Unfortunately, while Levaquin did closely follow the safety profile of ofloxacin, Levaquin was worse with respect to certain adverse effects, including tendon toxicity.

B. EPIDEMIOLOGY OF FLUOROQUINOLONE TENDON TOXICITY – OFLOXACIN IS MORE TENOTOXIC THAN THE REST, AND THE ELDERLY AND USERS OF CORTICOSTEROIDS ARE AT A HEIGHTENED RISK

28. Tendonitis as a side effect of fluoroquinolones was first reported in 1983. The first case of Achilles tendon rupture was reported in 1991 in conjunction with pefloxacin – a fluoroquinolone that has never been approved in the U.S, in part due to its teno-toxicity. Potentially due to pefloxacin's early use in France, by 1994, Dr. Pierfitte et al. identified over 100 French patients with fluoroquinolone tendon disorders (mostly pefloxacin), and was able to observe that tendon injury occurred more frequently in patients over 60 and especially in those who had received steroid therapy.

29. Although the Achilles tendon was affected the most, and bilaterally in many cases, Dr. Pierfitte reported that other tendons could by implicated as well. Accordingly, the French regulatory body was one of the first to notify physicians and their patients about the risk of fluoroquinolones-induced tendon injury. Additionally, as a likely result of Dr. Pierfitte's published observations, pefloxacin became severely restricted in use by 1995.

30. Once pefloxacin became restricted, Defendants' first generation ofloxacin emerged as the most tenotoxic fluoroquinolone on the market.

31. One of the first published reports regarding the tendon toxicity of ofloxacin was published in 1995 in the British Journal of Clinical Pharmacology (Wilton, L.V., Pearce, G.L. Mann, RD, *A comparison of ciprofloxacin, norfloxacin, ofloxacin, azithromycin and cefixime examined by observational cohort studies*. Br J Clin Pharmacol 1996; 41:277-284).

32. In the Wilton report, an analysis of prescription event monitoring data in the United Kingdom (a country where pefloxacin was not approved for market) revealed that ofloxacin was more tenotoxic than the other fluoroquinolones examined.

33. The United Kingdom's Regulatory Authority issued a bulletin, published in July 1995, stating that it had received 21 reports of tendon damage associated with fluoroquinolone

antibiotics. The Authority reported "elderly patients and those treated concurrently with corticosteroid are at particular risk."

34. Defendants submitted their New Drug Application regarding Levaquin to the FDA in 1995. Though they indicate that tendon disorders are associated with fluoroquinolone use, Defendants failed to report that ofloxacin was more tendon toxic than other currently marketed fluoroquinolones and failed to report that the tendon toxicity was exacerbated in the elderly, and especially in those taking corticosteroids.

35. The first epidemiological study to evaluate the relative risk of fluoroquinolone-induced tendonitis was published in 1999 by pharmacoepidemiologists and researchers at the Department of Epidemiology and Biostatistics and Internal Medicine at Erasmus Medical Center in Rotterdam. Van der Linden PD, Van de Lie J, Nab HW, Knok A, Stricker B H Ch, *Achilles tendonitis associated with fluoroquinolones*, Br J Clin Pharmacol 1999; 48: 433-437.

36. Data analyzed in this retrospective cohort study from 41 general practices in the Netherlands from 1995 and 1996 revealed that ofloxacin had the strongest association with Achilles tendonitis. The adjusted relative risk of tendonitis to fluoroquinolones was 3.7, while Achilles tendonitis associated with ofloxacin had a relative risk of 10.1. Upon information and belief, Defendants knew of this study and had an obligation to inform the FDA of this study by supplementing their New Drug Application.

37. A second epidemiological study published in 2002 by Van der Linden et al. analyzed data from the IMS Health database in the United Kingdom which contained general practice medical records on a source population of 1 to 2 million inhabitants. Van der Linden, PD, Sturdenboom MCJM, Herings, RMC, Leufkens HGM, Stricker BH Ch, *Fluoroquinolones and risk of Achilles tendon disorders: case control study*, BMJ 2002; 324:1306-1307.

38. In this nested case control study, the authors again found that ofloxacin was associated with an eleven fold increase in tendon disorders. More specifically, the authors found that the relative risk of Achilles tendon disorders following current use of fluoroquinolones was 1.9, but in patients over 60 years of age, the relative risk was 3.2. However, in the elderly, the relative risk was 11.5 for current use of ofloxacin, compared to 2.3 and 1.8 for ciprofloxacin and norfloxacin respectively. In patients of 60 years and older, concurrent use of corticosteroids and fluoroquinolones increased the risk to 6.2. Upon information and belief, Defendants knew of this study and had an obligation to inform the FDA of this study by supplementing their New Drug Application.

39. Soon thereafter, in 2003, Dr. van der Linden published her final epidemiological study, a larger population-based case control study that analyzed cases of Achilles tendon rupture and fluoroquinolone use from 1988 to 1998. Stunningly, her report concludes that the relative risk of a tendon injury in patients 60 years and older taking ofloxacin was 28.4 compared to ciprofloxacin's 3.6. He also found that use of corticosteroids nearly doubled the risk for tendon injury for patients over 60 years old.

40. Daiichi, the inventor of ofloxacin and Levaquin, published a 1997 rat study that admitted that Levaquin and ofloxacin were the most toxic to tendons of all the fluoroquinolones marketed in the United States. The study was designed to not only better understand the pathophysiological mechanism of fluoroquinolone-induced tendon disorders, but also to compare the relative tendon toxicity of ten different fluoroquinolones.

41. Although the exact mechanism of how fluoroquinolones cause tendon injury is still being investigated, studies have suggested that fluoroquinolones can degrade tendon cells by causing apoptosis, or a programmable cell death, and therefore lose their integrity, and easily tear and/or rupture.

42. The outcome of Achilles tendon ruptures in persons over 60 – the population most affected by this adverse reaction, is not favorable. Treatment may include a corticosteroid to decrease inflammation -- the very drug that, when combined with a fluoroquinolone, can dramatically increase the risk of a tendon rupture. In the event of a tendon rupture, the leg is often immobilized through a boot or other casting for anywhere between six weeks to six months, and physical therapy is ordered thereafter. Surgery is frequently not recommended in the elderly population due to poor recovery rates. However, even with immobilization for long periods of time and physical therapy, the Achilles tendons in the elderly rarely fully recover. The adverse effects, however, also occur in patients who are age 60 or less.

C. THE FIRST U.S. TENDON WARNING

43. According to the U.S. consumer watchdog organization, Public Citizen, by 1996 there were over 130 reports of tendon injury from around the world over a ten year period and 52 reports of tendon injury in the United States associated with fluoroquinolone use.

44. As there was no mention of any fluoroquinolone-induced tendon injury on the label, Public Citizen petitioned the FDA in 1996, based on the number of adverse event reports world wide, to require that manufacturers of fluoroquinolones revise their product label to alert physicians of this unusual adverse event.

45. The FDA responded by requiring the following class warning on all fluoroquinolone labels:

> "Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with [the specific drug name].[The specific drug name] should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur at any time during or after therapy with [the specific drug name]."

46. By 1997, U.S. manufacturers of fluoroquinolones had modified their label. However, the label was buried in a long list of potential adverse reactions; it was not highlighted in any way, such as with bold lettering, or even a heading titled "tendon injury." Moreover, no mention was made of the fact that age and corticosteroid use tripled the risk of tendon injury. No letter to physicians was disseminated, and Defendants did not highlight this unusual effect when promoting Levaquin to doctors.

D. LEVAQUIN'S EARLY POST-MARKET EXPERIENCE

47. Levaquin was first introduced in Japan in 1993 and later introduced in the United States in 1997.

48. As has previously been alleged and described, before Levaquin's market launch in the United States, Defendants had knowledge that:

a. Levaquin would be as toxic as ofloxacin;

b. Ofloxacin was revealing itself as one of the most tenotoxic fluoroquinolones on the market; and

c. The elderly, and especially those using corticosteroids, were at least three times as likely to suffer a tendon injury.

49. Despite this unique knowledge, Defendants chose to use the same label that the FDA required on all other fluoroquinolones. Accordingly, in 1997, most U.S. physicians did not understand fluoroquinolone tendon toxicity, and were completely ignorant of the elderly's exceptional vulnerability to this antibiotic, especially those dependent on corticosteroids.

50. A look at Defendants' sales materials could explain why: the very group that Levaquin was most toxic to was the very market Defendants were after. Defendants' target market for Levaquin was the elderly – especially those with upper respiratory infections who were likely to be chronic corticosteroid users.

51. More disturbing, Defendants' promotional campaign was themed on Levaquin's excellent safety profile and failed to disclose the risks of tendon injury.

52. Defendants capitalized on Levaquin's early introduction into Japan and other countries by using pre-U.S. prescription sales data to assert that Levaquin had been prescribed frequently with few adverse events.

53. For example, one such advertisement boasted that Levaquin had "An Outstanding Record of Safety" as "[o]ver 63,000,000 patients worldwide" had taken the drug and only diarrhea and nausea had shown up as adverse effects, albeit rarely.

54. Cleverly, the promotional literature only reported on adverse events in U.S. *clinical trials* where only a very small sampling of patients took their drug, and where many adverse events do not necessarily reveal themselves. So, Defendants claimed "proven performance" on the 63,000,000 million people that had used Levaquin outside the United States, but chose not to disclose the adverse events that were being reported on this same population.

55. As Levaquin gained traction, its "Achilles heel" of heightened tenotoxicity revealed itself.

56. Levaquin enjoyed immediate popularity in the Italian market. Introduced to Italy in 1998, Levaquin became Italy's best selling fluoroquinolone, surpassing Cipro, the major market leader, in just three years. Curiously, ofloxacin, Defendant's previous fluoroquinolone, had the lowest market share, which was consistent with Daiichi's plan to "cannibalize" ofloxacin in favor of Levaquin.

57. One of the first comparative studies that included post market experience with Levaquin was from Italy. The authors analyzed Italian adverse event data from 1999 to 2001 to help determine the relative toxicity of each marketed fluoroquinolone antibiotic.

58. The Italian study was published in 2003 and revealed 1) the most frequently reported serious reaction to fluoroquinolones were tendon disorders; 2) levofloxacin was the fluoroquinolone with the highest tendonitis reporting rate; and 3) levofloxacin ranked first for tendonitis reports during the same period in the World Health Organization's adverse event database, with 522 reports of levofloxacin-induced tendon disorders and ruptures.

59. Not surprisingly, in March 2002, the Italian Health Ministry issued a Dear Doctor letter to inform physicians of the risk of Levaquin tendon rupture.

60. France also reported a particularly large amount of tendon disorders soon after Levaquin was first marketed to that country in September 2000. By June 2001, in just nine months, 333 adverse reactions had been reported, with tendon disorder being the most frequently reported adverse event. Again, the adverse event data supported the epidemiological evidence finding that tendon injuries were more prominent in the elderly, especially when there had been co-administration of corticosteroids.

61. France's regulatory authority published a Dear Doctor letter to highlight this information in 2002.

62. Similarly, the Belgian regulatory authority received 161 reports of Levaquin-induced tendon injury, including 68 reports of tendon rupture, in the first two years of Levaquin's introduction to Belgium. Again, the average age of patients with levofloxacin-associated tendinopathy was 69 years old and about half were receiving concomitant corticosteroid treatment. As with other adverse event data, the tendon injuries were reported to occur soon after Levaquin was ingested. Belgium also noted, similar to Italy, that the number of tendon disorders associated with levofloxacin was much higher than that of the other quinolones. Not surprisingly, ofloxacin had the second highest reports of tendon injury.

63. Recognizing that the number of tendon effects from Levaquin were far more frequent that any of the older fluoroquinolones which had all been on the market over the past ten years, the Belgium regulatory authority also disseminated a Dear Doctor letter in 2002 highlighting their concerns about levofloxacin's toxicity and suggesting that levofloxacin is only justified for the treatment of community-acquired pneumonia in patients who are allergic to beta-lactams. The agency stressed the elderly and people who used corticosteroids were particularly at risk and encouraged doctors that if levofloxacin treatment was necessary, to watch for tendon injury.

64. After nearly five years on the market in the United States, and following the post-marketing data out of Europe, Defendants finally decided to update their tendon warning.

E. LEVAQUIN'S SECOND TENDON WARNING

65. The pre-2002 Levaquin label bore the required tendon warning from its market launch in 1997. It was the last of the warnings listed, with no header or any other identification to alert a practitioner to this unusual side effect. The warning was behind gastrointestinal affects, hypersensitivity reactions, and even the rare event of anaphylactic shock.

66. In 2002, Defendants embedded the following in the existing tendon warning: "Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly."

67. Through an international database managed by Daiichi, Defendants had access to the post market surveillance data all over the world, and specifically France, Belgium, Italy, and the United Kingdom.

68. By 2002, the adverse event data in all those countries consistently and unequivocally revealed that the risk of tendon injury was nearly triple for people over 60 as compared to people under 60. Additionally, Defendants had knowledge of at least one

epidemiological study confirming the age effects of fluoroquinolone use. All data pointed to the fact that Levaquin was more tendon toxic than all other fluoroquinolones.

69. Despite a wealth of information, Defendants chose not to warn their target patient population – the elderly -- with their 2002 warning. Instead, they muted their additional tendon warning by flipping the confounders. Rather than warn that the risk of tendon injury was increased (tripled) in the elderly, the warning stated that that the risk was possibly increased in those using corticosteroids. According to Defendants' warning, any elderly person not on corticosteroids therefore had no additional risk of a tendon injury, and the fact that the warning was so equivocal regarding corticosteroids diffused any possible effect of adequately warning physicians of the effect of age on the frequency and severity of this debilitating injury, as well as adequately warning about the risks of concomitant use of corticosteroids. Thus the warning was insufficient to warn about the both the risk factors of age and co-medication with corticosteroids.

70. Nor did Defendants make any effort to highlight this new information to its prescribing doctors -- Defendants did not send any Dear Doctor letters regarding the 2002 label change to any healthcare practitioners, as had been done in Italy, Belgium, and France.

71. Accordingly, despite the 2002 label change, Levaquin prescriptions only increased, and tendon injuries mounted.

F. DEFENDANTS THWART EFFORTS TO HIGHLIGHT LEVAQUIN'S INCREASED RISK OF TENDON INJURY

72. Alarmed by the early post market experience with Levaquin, France, Belgium, Italy, the United Kingdom and other European countries convened before the European Agency for the Evaluation of Medicinal Products (EMEA) as early as September 2001 to discuss a heightened warning for levofloxacin.

73. The EMEA proposal was that levofloxacin would be singled out as the most tendon toxic of the fluoroquinolones with a warning that stated that levofloxacin (marketed

under the brand name Tavanic) was associated with a greater frequency of tendinopathy and tendon rupture than other fluoroquinolones.

74. Aventis Pharmaceutical was the manufacturer and distributor of levofloxacin in Europe.

75. Under increasing pressure to agree to the proposed changes to the warning label, Aventis conducted two epidemiological studies in Europe regarding the relative tendon toxicity of levofloxacin. The first study used the United Kingdom's General Practitioners Research Database of medical records from 1997 through 2001, and the second used Germany's Mediplus database of medical records from 1998 to 2001.

76. Before releasing the results of the two epidemiology studies to the European regulatory authorities, and ostensibly because of the results of the studies, Aventis contracted with Defendants, specifically JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, to fund and co-author a study in the United States on tendon rupture and fluoroquinolones.

77. Advocating that the U.S. Study would be the largest epidemiological study to date and therefore provide the most definitive evidence of the relative risk of levofloxacin and tendon injury, and that the European studies to date were too small from which to base a label change, Aventis convinced the European regulatory authorities to forestall the proposed warning change until the preliminary data from the U.S. study was released.

78. In or around April 2002, Aventis submitted the results of their two European epidemiological studies to the United Kingdom's regulatory authority, the Medicines and Healthcare Products Regulatory Agency (MHRA).

79. The epidemiology studies conducted by Aventis in Europe concluded that levofloxacin was associated with a higher rate of tendon injury than all the other

fluoroquinolones compared. Ofloxacin, the fluoroquinolone indicted in early epidemiological studies as the most teno-toxic, came in second.

80. An assessor at the MHRA concluded that the two epidemiological studies had findings "supporting a signal generated by spontaneous reporting with respect to an increased risk of tendinopathy with levofloxacin compared to other fluoroquinolones."

81. Moreover, the assessor remarked "the finding that ofloxacin (the racemate) is associated with an intermediate level of risk makes pharmacological sense, suggesting that the L- rather than the D-isomer of ofloxacin is likely to be responsible for tendon toxicity….given the consistency and plausibility of the findings, a real difference is the most likely explanation."

82. By the time Aventis released the results of their epidemiological studies, the preliminary results of the U.S. study was reportedly only six months away. Accordingly, the European regulatory authorities agreed to wait before forcing a label change.

83. The U.S. epidemiological study was funded and co-authored by Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT.

84. Unlike the healthcare databases in Europe which contain computerized medical records, JOHNSON & JOHNSON PRD used data from the Ingenix Research database which consisted of U.S. health insurance claims data from 1997 to 2001. The study analyzed only Achilles tendon ruptures and sought to examine whether fluoroquinolone exposure was a risk factor for this injury. It did not assess the relative risk of Levaquin tendon toxicity, as had been requested by the United Kingdom.

85. Under the guise of data validation, Defendant JOHNSON & JOHNSON PRD created an algorithm that conveniently excluded nearly 70 percent of health claims for elderly persons who suffered Achilles tendon rupture.

86. The algorithm used CPT procedure codes that only related to surgical repair which thereby excluded all those Achilles tendon rupture cases where the patient was casted or booted, as is the case in the elderly population.

87. By manipulating the data, Defendant JOHNSON & JOHNSON PRD was able to exclude the very group that was most prone to tendon rupture.

88. Not surprisingly, the results of the U.S. epidemiological study – the study upon which regulatory action hinged in Europe, with ramifications to the U.S. market – revealed for the first time that there was no increased risk of Achilles tendon rupture associated with any fluoroquinolone use. Neither the confounders of age nor corticosteroid use altered these findings.

89. Indeed, when one includes the data that was excluded by the algorithm, the result becomes consistent with the approximately eight other epidemiological studies performed on the topic. See Seeger et al. *Achilles Tendon Rupture and its Associations with Fluoroquinolone Antibiotics and Other Potential Risk Factors in a Managed Care Population*, Pharmacoepidemiology and Drug Safety 2006; 15: 784-792 ("There was a stronger association with fluoroquinolone antibiotic exposure among these "ruled-out" cases of ATR . . than among the decision rule confirmed cases. This association was stronger with exposure close to the date of the rupture and was more pronounced among the elderly.")

90. As a result of Defendants' misrepresentations in the U.S. Study, the MHRA and the other European regulatory agencies chose not to revise the levofloxacin label as they had previously recommended.

G. DEFENDANTS DOWNPLAY THE RISK OF LEVAQUIN TO PHYSICIANS

91. Consistent with their plan to downplay Levaquin's known risk of tendon injury, Defendants made no attempts to educate physicians in the United States about this unusual

adverse event. Although Dear Doctors had been widely disseminated throughout Europe advising of Levaquin's tendon toxicity and the vulnerability of this adverse event to the elderly, Defendants did not so advise the U.S. physicians.

92. Defendants' plan was to hide behind the class warning and blame any tendon injuries reported on the general or class pharmacological properties of a fluoroquinolone antibiotic rather than on the L-isomer of the ofloxacin compound as the Aventis studies suggested.

93. Promotional material designed and distributed by Defendants, and more specifically by ORTHO-McNEIL, consistently omits the risk of tendon injury on materials left with physicians.

94. Accordingly, physicians continued to prescribe Levaquin believing it to have the same safety profile as Cipro and unaware of the heightened adverse effect of Levaquin on the elderly population, as well as its heightened effect on patients who are also were prescribed a corticosteroid medication.

H. AN EXPLOSION OF TENDON INJURIES RESULTS IN THIRD LABEL CHANGE

95. A review of the events in the FDA Adverse Event database from 1997 through 2005 *for Levaquin alone*, showed 1,044 reports of tendon injuries with 282 reports of tendon rupture. This six year figure for tendon affects associated with Levaquin far surpassed the ten year history of tendon effects from 1985 through 1995 associated with all pre-Levaquin fluoroquinolones.

96. After generic versions of Cipro went on the market in 2003, Levaquin became the number one prescribed fluoroquinolone in the United States. And when generic versions of Zithromax, a highly popular macrolide antibiotic, went on the market after its patent expired in 2005, Levaquin then became the number one prescribed antibiotic in the world in 2006.

97. Corresponding with Levaquin's increased popularity, the number of adverse events reported to the FDA reported soared. 143 tendon related injuries were reported in 2006, and in just the first quarter 2007, 107 tendon related injuries were reported where Levaquin was the primary suspect.

98. The Levaquin phenomenon did not go unnoticed by the Illinois Attorney General. On May 18, 2005, the Illinois Attorney General submitted a petition to the FDA requesting a black box warning be added to fluoroquinolone medications' label. The Illinois Attorney General suggested that the black box warning was necessary in order to highlight the seriousness of tendon injuries and that the risk is increased in the elderly and in patients on corticosteroids.

99. The Illinois Attorney General also requested that the manufacturer issue a Dear Doctor letter to inform the health care providers about this significant hazard to health, as the tenotoxic affects of fluoroquinolones were not well known to practicing physicians.

100. In the Petition, the Attorney General's office reviewed the literature and further stated that tendon injuries were not a rare complication of fluoroquinolone use. The Petition also complained that the current tendon warning was "buried in lists of potential side effects which are both less frequent and less severe."

101. One year later, Public Citizen, the same consumer watchdog organization that petitioned the FDA in 1996 for a tendon warning, again petitioned the FDA saying the first tendon warning did not go far enough. Citing the alarming increase in reports of tendon injury, joined the Illinois Attorney General's petition and urged that the FDA place a black box warning regarding the risk of tendonitis and tendon rupture.

102. At the request of the FDA, in April 2007, the Levaquin label changed for a third time with regard to tendon injuries. The new label warning is not a black box warning. It now states that indeed the elderly are at an increased risk of tendon injury, and unequivocally states

that the risk is increased with concomitant use of corticosteroids, contrary to the results of Defendant's Ingenix study.

103. Upon information and belief, Defendants negotiated with the FDA over the warning change and insisted on a class warning to thereby diffuse and minimize the particular heightened risk of tendon injury with Levaquin.

104. The warning in effect at the time of Plaintiff's injury was inadequate and failed to alert Plaintiff's physicians and prescribing health care providers that Levaquin is more toxic to the tendons than other antibiotics, including fluoroquinolones, available in the U.S. market. At the time of Plaintiff's injury, health care providers had no adequate warning that Levaquin is much more tenotoxic than other drugs in the class and therefore will interpret the relative risk of a Levaquin-induced tendon injury inappropriately.

105. On July 8, 2008, the FDA notified Defendant of the need to add a black box warning to its label concerning tendon disorders. That warning applied to patients of all ages, but particularly to those over age 60, and stated, in part: Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Defendant waited an additional four months, and finally in November 2008 issued a Dear Doctor letter advising physicians of the black box warning. This black box warning could have, and should have, been provided to physicians prior to the time of Plaintiff's injury.

Defendants continue to market Levaquin as a first line therapy for the common bronchitis and sinusitis infections, and for which many other safer antibiotics are available.

SPECIFIC FACTUAL ALLEGATIONS

106. VICKIE QUAID was 51 years of age when she was prescribed and began consuming Levaquin in March 2009 to treat an infection. After using Levaquin, she suffered a

tendon rupture in her hand. Prior to suffering a tendon rupture in her hand, Ms. VICKIE QUAID was able to perform all activities of daily living independently. As a direct and proximate cause of her Levaquin-induced tendon rupture in her hand, Plaintiff VICKIE QUAID has suffered significant pain and suffering, and her ability to perform normal daily tasks has been compromised and her quality of life has been severely diminished.

FIRST CAUSE OF ACTION
STRICT LIABILITY

107. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

108. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Levaquin. Defendants designed, manufactured, marketed, and sold Levaquin to medical professionals and their patients, knowing it would be ingested for the treatment of infections.

109. Levaquin as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

110. Levaquin was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Levaquin were in a condition not suitable for their proper and intended use among patients.

111. Levaquin was used in the manner for which it was intended, that is, for treatment of bacterial infections. This use resulted in injury to Plaintiff.

112. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of Levaquin. Further, in no way could Plaintiff

have known that Defendants had designed, developed, and manufactured Levaquin in such a way as to increase the risk of harm or injury to the recipients of Levaquin.

113. Levaquin is defective in design because of its propensity to cause tendon ruptures and other serious tendon injuries.

114. Levaquin is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia,* the propensity of Levaquin to cause serious tendon injuries; the post-marketing experience with Levaquin; the increased risk of tendon injury in patients over the age of 60; the numbers of tendon-related adverse events reported; and the probability of suffering an acute tendon injury when ingesting corticosteroids concomitantly with Levaquin or post-Levaquin use.

115. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Levaquin to Plaintiff.

116. Defendants had knowledge and information confirming the defective and dangerous nature of Levaquin. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and her physicians that Levaquin causes serious tendon injuries including, without limitation, tendon rupture.

117. As a direct and proximate result of Defendants' wrongful conduct, including Levaquin's defective and dangerous design and inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
NEGLIGENCE

118. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

119. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Levaquin, including a duty to ensure that Levaquin did not pose a significantly increased risk of bodily injury to its users.

120. Defendants had a duty to exercise reasonable care in the advertising and sale of Levaquin, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Levaquin that were known or should have been known to Defendants at the time of the sale of Levaquin to the Plaintiff.

121. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Levaquin because Defendants knew or should have known that Levaquin had a propensity to cause serious injury, including tendon rupture and other serious tendon injuries.

122. Defendants failed to exercise ordinary care in the labeling of Levaquin and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, without limitation, tendon rupture.

123. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

124. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

125. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and

distribution of Levaquin, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

126. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

127. Defendants designed, formulated, tested, manufactured, marketed, sold, and distributed Levaquin as has previously been alleged and described herein.

128. At the time Defendants marketed, sold and distributed Levaquin, Defendants knew of the use for which Levaquin was intended and impliedly warranted that Levaquin was merchantable, safe and fit for its intended purpose: namely that Plaintiff could ingest Levaquin without the risk of serious injury.

129. Plaintiff, foreseeable users of Levaquin, and Plaintiff's physician(s), reasonably relied upon Defendants' judgment and implied warranties in purchasing and consuming Levaquin as intended.

130. Levaquin was defective, unmerchantable, and unfit for ordinary use when sold, and subjected Plaintiff to severe and permanent injuries.

131. Defendants breached their implied warranties because Levaquin was and continues to be neither of merchantable quality nor safe for its intended use in that Levaquin has the propensity to cause tendon rupture, other debilitating tendon injuries, and bodily harm.

132. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness for its intended purpose, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

133. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

134. Defendants through their marketing program, promotional activities, product labeling, package inserts, and other written and verbal assurances expressly warranted to physicians and consumers, including Plaintiff and/or her physicians, that Levaquin had been shown by scientific study to be safe for its intended use.

135. Plaintiff, and/or her physicians, reasonably relied upon Defendants' express warranties in purchasing consuming, and prescribing Levaquin.

136. Defendants breached their express warranties because Levaquin as manufactured and sold by Defendants does not conform to these express representations in that Levaquin has a propensity to cause tendon rupture, other serious tendon injuries, and bodily harm.

137. As a direct and proximate result of Defendants' breach of their express warranties, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
FRAUD

138. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

139. Defendants were under a duty and failed to discharge their duty to exercise reasonable care to disclose to Plaintiff and her doctors the defective nature and risks that Levaquin can cause severe and permanent injuries, including, without limitation, tendon ruptures, of which they had special knowledge not available to Plaintiff or her doctors, and as to which they made affirmative representations in violation of all applicable laws, and concealed material facts relating to the defective nature and risks of Levaquin, which were peculiarly within its knowledge, knowing that Plaintiff and her doctors would rely on the presumption that no such facts exist.

140. Defendants knew that Levaquin can cause severe and permanent injuries, including, without limitation, tendon ruptures; indeed, Defendants knew that tendon injuries associated with Levaquin had occurred for years. Defendants had actual knowledge at the time of sale of Levaquin to the Plaintiff that Levaquin created a risk of serious bodily injury to its users, including, without limitation, tendon injuries, based, in part, upon test results, studies, adverse reaction reports, regulatory action in foreign countries, published reports, and their own clinical trials and post-marketing surveillance of Levaquin and its molecularly similar counterpart, ofloxacin.

141. At all times during the course of dealing between Defendants and Plaintiff, Defendants knowingly and recklessly omitted and concealed information peculiarly within their knowledge to the Plaintiff, her doctors, the scientific community and to the general public - e.g.,

the dangers of Levaquin, including the special risk of tendon injury and tendon ruptures, particularly to the elderly - knowing that the scientific community, the general public, the Plaintiff and her doctors, would rely on the presumption that the dangers did not exist.

142. Defendants actively concealed from the Plaintiff, her doctors, the scientific community and the general public:

i. that their own test results, published studies, and/or clinical trials showed a statistically high risk of serious tendon injuries associated with Levaquin including, without limitation, tendon ruptures; and/or

ii. that Levaquin was not adequately tested for serious tendon injuries before or after its introduction on the market; and/or

iii. that Levaquin was, in fact, unsafe as it posed a risk of injury which outweighed any purported benefits.

143. Defendants misrepresented that Levaquin was safe and effective for its intended uses by affirmative misrepresentation, and/or actively concealment and omission of material facts regarding the safety and effectiveness of Levaquin, and by their course of conscious or intentional conduct succeeded in selling and marketing dangerous, defective, and ineffective antibiotics to be ingested by Plaintiff. Defendants intentionally omitted, concealed and/or suppressed this information from consumers, including Plaintiff and her doctors, in order to avoid losses in sales to consumers and market share to its major competitors.

144. Moreover, Defendants engaged in an aggressive marketing strategy, which included false representations regarding the safety profile and known adverse side effects of Levaquin to create the impression and to convey to Plaintiff and the general public that:

i. Levaquin had a favorable safety profile and was fit for human consumption;

ii. the benefits of taking Levaquin outweighed any associated risks; and

iii. the use of Levaquin was safe and had fewer adverse health and side effects than were known or should have been known by Defendants at the time of these representations.

145. The omissions, misrepresentations and concealment described in the preceding paragraphs occurred, without limitation, in the Levaquin warning labels, advertisements and promotional materials, in the Johnson & Johnson funded or created scientific reports, and the failure to provide other special notification of the dangers of Levaquin to the Plaintiff or her physicians, for example, Dear Doctor letters. The Defendants' statements omitted, concealed, and misrepresented the dangers of serious injury, including, but not limited to, tendon ruptures, particularly to the elderly, to Plaintiff and her prescribing doctors.

146. Defendants engaged in fraud by deliberately and affirmatively concealing and failing to disclose adverse reactions of Levaquin to Plaintiff, her doctors, the scientific community, and the general public, and by disseminating only positive and misleading scientific data, and by concealing scientific data that showed increased risk of tendon-related injury, to Plaintiff, her doctors, the scientific community, and the general public.

147. Plaintiff VICKIE QUAID, and her physician, Dr. Andrew Kirkpatrick relied on the warning labels as they appeared in the patient package insert at the time they prescribed or consumed Levaquin. The applicable warnings concealed and omitted material facts relating to the defective nature and risks of Levaquin. These dangers were peculiarly within the Defendants' knowledge, and were omitted and concealed knowing that Plaintiff and her doctors would rely on the presumption that no such facts exist.

148. Defendants knew or should have known that their representations and omissions regarding the safety of Levaquin were, in fact, false and/or misleading, and actively made such representations and omissions with the intent, design, and purpose that Plaintiff and others,

including prescribing physicians, rely on these representations leading to the prescription, purchase and consumption of Levaquin.

149. At all times herein, Plaintiff and her physicians were unaware of the dangers of Levaquin with respect to tendon ruptures, including the special risk of tendon injury to the elderly, and were reasonably misled by the Defendants' omission of information about this danger.

150. At all times herein, Plaintiff and her physicians were unaware of the falsity underlying Defendants' statements and reasonably believed Defendants' false statements about the safety and efficacy of Levaquin to be true.

151. Plaintiff and her doctors could not have discovered Defendants' fraudulent and misleading conduct at an earlier date through the exercise of reasonable diligence because Defendants actively concealed their deceptive, misleading and unlawful activities.

152. Plaintiff and her physicians did, and could be expected to, reasonably and justifiably rely on Defendants' representations and omissions because Defendants held themselves out as having expertise and specialized knowledge in the pharmaceutical industry.

153. Plaintiff justifiably relied upon to her detriment and/or were induced by Defendants' false statements and active concealment over the safety of Levaquin, in part, because at no time did Plaintiff or her physicians have the knowledge or expertise necessary to independently evaluate the safety of Levaquin.

154. Defendants' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately, or recklessly, in order to induce Plaintiff to purchase Levaquin and Plaintiff and her physicians did reasonably and justifiably rely upon the material misrepresentations and missions made by the Defendants about Levaquin when agreeing to purchase and/or ingest Levaquin.

155. As a direct and proximate result of Defendants' false representations and/or active concealment of material facts regarding the safety and efficacy of Levaquin, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICES ACTS

156. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

157. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of Levaquin.

158. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Levaquin, and would not have incurred related medical costs. Specifically, Plaintiff VICKIE QUAID, her physician, Dr. Andrew Kirkpatrick, Trinity Mother Frances Hospital, 910 E. Houston St., Tyle, TX 75702, and his staff were misled by the deceptive conduct described herein.

159. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

160. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for Levaquin that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

161. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of:

i. Minn. Stat. Ann. § 325D.13 and § 325D.44 *et seq*.; and

ii. Tex. Bus. & Com. Code § 17.41, *et seq*.

162. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell Levaquin. Each aspect of Defendants' conduct combined to artificially create sales of Levaquin.

163. The medical community relied upon Defendants' misrepresentations and omissions in determining which antibiotic to utilize.

164. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

165. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for Levaquin.

166. As a direct and proximate result of Defendants' violations of Minnesota's and Texas's unfair trade practice acts, Plaintiff has sustained economic losses and other damages for which they are entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
VIOLATION OF TEXAS'S CONSUMER FRAUD ACT

167. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

168. Defendants acted, used, and/or employed fraud, false pretense, false promise, misrepresentation, misleading statements and/or deceptive practices, concerning the safety, use,

efficacy, and testing of Levaquin with the intent that others, including Plaintiff, rely upon those false and deceptive acts in determining whether to use Levaquin.

169. In its marketing, direct-to-consumer advertising, promotion, sale, and distribution of Levaquin, Defendants knowingly, unfairly, and deceptively promised and represented that Levaquin is a safe and effective antibiotic while failing to disclose the known properties, ingredients, characteristics, qualities and risks associated with Levaquin when the Defendants had actual knowledge or should have known of the serious adverse health effects associated with Levaquin, including but not limited to, tendon ruptures.

170. Defendants made such misrepresentations and omissions of material fact with the intent, design, and purpose that consumers, including Plaintiff, rely on such representations in choosing to purchase Levaquin.

171. As a direct and proximate result of Defendants' fraudulent sale and marketing, Plaintiff ingested Levaquin, and suffered severe and debilitating injuries and economic loss, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering.

EIGHTH CAUSE OF ACTION
UNJUST ENRICHMENT

172. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

173. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and implementation of Levaquin by Plaintiff.

174. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the

quality, nature, or fitness that had been represented by Defendants, or that Plaintiff, as a reasonable consumer, expected to receive.

175. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

4. Double or triple damages as allowed by law;

5. Attorneys' fees, expenses, and costs of this action;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: March 1, 2011

Respectfully submitted,

ZIMMERMAN REED P.L.L.P.

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